Eur J Vasc Endovasc Surg **28**, 138–141 (2004)
doi: 10.1016/j.ejvs.2004.02.020, available online at http://www.sciencedirect.com on SCIENCE DIRECT®

# Subintimal Angioplasty: Feasible and Durable

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***Objective.*** *To assess prospectively the feasibility and durability of subintimal angioplasty (SA) clinically and by duplex scans every 3 months.*
***Patients and methods.*** *Within a period of 54 months, we selected 96 patients with 100 occlusions (mean length: 11.5 cm) of femoro-popliteal or tibial arteries, for SA.*
***Results.*** *The technical success rate was 88% and seven out of 12 failures were treated by conventional surgery. Five below-the-knee amputations were performed despite a patent recanalization. The following complications occurred: arterial perforation (6), arterial thrombosis (4), extensions beyond the planned re-entry site (5), and arterial dissection (2). Primary, assisted-primary and secondary patency rates were 61, 68 and 74%, respectively at 24 months. The 24 month-limb salvage and survival rates were 78 and 85%, respectively. Duplex imaging demonstrated 10 restenosis (five symptomatic > 70%, five asymptomatic 30–70%), seven occlusions (five asymptomatic, two symptomatic treated by a bypass) and one asymptomatic dilatation.*
***Conclusion.*** *In a selected group of patients SA is feasible with a high initial technical success rate. SA is a good alternative in patients who are poor candidates for bypass surgery.*

*Key Words: Subintimal angioplasty.*

## Introduction

Intraluminal angioplasty is currently considered as the treatment of choice of short femoro-popliteal stenosis.[1] However, for long femoro-popliteal occlusions treated by this technique, the patency rates are poor[2] and bypass surgery remains the procedure of choice.[1] The development of subintimal angioplasty (SA) allows long femoro-popliteal occlusions[3] and infra-popliteal artery disease[4] to be treated. In a group of 200 consecutive patients with long femoro-popliteal occlusions treated by SA, a 12 months clinical patency rate of 71% was reported.[5] Other institutions have shown comparable initial success rates, with a primary and secondary patency of 59 and 65%, respectively at 2 years.[6] During follow-up, clinical presentation and ankle–brachial indices were the only studies routinely performed and, therefore, the anatomical success of the technique was not reported. We have prospectively analysed the outcome of consecutive patients treated by SA clinically and by duplex every 3 months in order to assess the feasibility and further evaluate the long-term durability of this technique.

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## Patients and Methods

From November 1, 1998, to April 10, 2003, we selected 96 patients with 100 occlusions of femoro-popliteal or tibial arteries, for SA (mean age: 72 years; range 44–90). This subset represents 12.7% of 785 total infra-inguinal revascularizations performed over the 5-year period in our unit. The demographic data of the patients are shown in Table 1. All patients were followed at 3-month intervals by means of clinical and duplex ultrasound examination. Arteries identified with duplex abnormalities were evaluated with angiography. A PTA was proposed if the arteriogram confirmed the area of restenosis. A bypass was proposed in cases of occlusion.

### *Technique*

All patients underwent a diagnostic angiogram. The following factors were used to select patients for SA:

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**Table 1.**

| Demographic data | *n* | % |
|---|---|---|
| Claudication | 46 | 48 |
| Critical limb ischemia | 50 | 52 |
| Smocking | 62 | 64 |
| Diabetes | 63 | 66 |
| Hypertension | 69 | 72 |
| Coronary artery disease | 38 | 40 |
| Site of occlusions | | |
| Femoro-popliteal | 82 | 82 |
| Tibial | 18 | 18 |
| Length of occlusion | | |
| > 10 cm | 31 | 31 |
| 5–10 cm | 63 | 63 |
| < 5 cm | 6 | 6 |
| Mean (cm) | 11.5 (4–40) | |

lack of vein available for bypass, severe medical co-morbidities, long standing femoro-popliteal or tibial occlusion with a good starting stump and the presence of at least one correct distal run-off vessel. We used the technique of Bolia with slight modification. The ipsilateral common femoral artery was punctured anterogradely and followed by the insertion of a 6 French introducer (Terumo, Tokyo, Japan). Systemic heparin (50 units/kg) was then given. In case of an occlusion shorter than 5 cm, a transluminal recanalization was attempted first with the help of a hydrophilic guidewire (180 cm long, 0.035 in. diameter and angled, Terumo). For occlusions longer than 5 cm or where transluminal angioplasty had failed, SA was attempted. Then a 5F Van Andel predilating catheter (Cook, Charenton, France) was introduced up to the start of the occlusion. Then the occlusion was crossed using the combination of a Terumo wire making a loop and a Van Andel Catheter until the point of re-entry within the true arterial lumen. At the beginning of our experience (first 46 patients), once the lesion was crossed, a 5F balloon catheter of 3–6 mm diameter and 2–4 cm long was inflated throughout the entire length of the subintimal channel using 10–12 pressure atmospheres at 10-second inflations. Now, we perform brief inflations at low pressure. For vessels of less than 4-mm diameter, the Terumo wire was exchanged for a 0.014 wire (Spartacore, Guidant, Rueil Malmaison, France) and a monorail balloon (Herculink, Guidant, France) was mounted. Technical success was defined as a recanalization with 30% or less residual stenosis and antegrade flow on completion angiogram. After successful recanalization, all patients received aspirin at 250 mg/day and clopidogrel (plavix) for 1 month, followed by aspirin alone.

## Results

### *Immediate results*

Technical success was achieved in 88 out of 100 cases (88%). The technical failures were due to inability to enter the subintimal space ($n = 2$), failure to progress the wire in a calcified vessel ($n = 3$) and failure to re-enter the distal lumen ($n = 7$). Five (intermittent claudication three, critical limb ischaemia two) out of 12 failures were not surgically treated because the limb was clinically improved. Seven failures needed a bypass. In three cases, we had to perform longer bypasses than scheduled from above knee to below knee because of the extension of the dissection lower than the end of the occlusion in order to achieve re-entry.

Immediate clinical success (defined as the freedom of claudication among the claudicants or the improvement of patients in CLI i.e. the absence of amputation) was achieved in 80/100 cases. In five cases, we performed a below knee amputations despite technical success.

Seventeen immediate complications were observed (17%): non-severe perforations (requiring neither blood transfusion nor reoperation) ($n = 6$), extension of the dissection beyond the planned re-entry site superior to 5 cm ($n = 4$) (Fig. 1), thrombosis treated by thrombolysis ($n = 5$), threatening dissection treated by a stent ($n = 2$).

### *Long-term results*

The mean follow-up time was 14.5 months and 14 patients were lost to follow-up (15%). Primary, assisted-primary and secondary patency rates were 61, 69 and 74%, respectively at 24 months (Fig. 2). The 24 month-limb salvage rate was 78% and survival rate was 85%. Eighteen morphologic abnormalities (18%) were observed by duplex: 10 restenoses (five symptomatic > 70%, that were treated by a new PTA (Fig. 3), five asymptomatic 30–70% that were not redilated), seven occlusions (five asymptomatic, two symptomatic treated by distal bypass) and one asymptomatic dilatation.

## Discussion

Similar to other investigators, we have shown SA to be feasbile for long occlusions.[7,8] We have confirmed that SA is simple in the presence of a good starting stump, the absence of a heavily calcified occlusion and at least

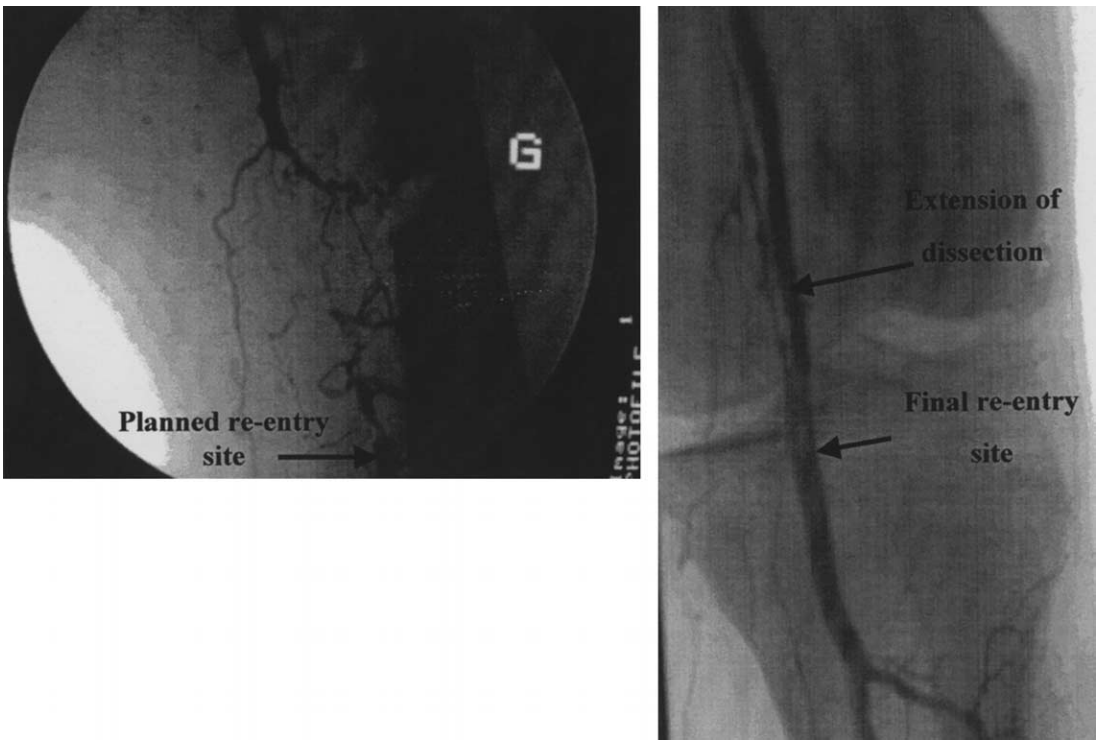


**Fig. 1.** Left: occlusion of the distal superficial femoral artery. The planned re-entry site is located at the hunter's canal. Right: successful recanalization but extension of the dissection beyond planned re-entry site and final re-entry site located at the level of the infra-popliteal artery.

one patent distal run-off vessel. SA offers many advantages compared to conventional bypass surgery. SA is minimally invasive and a fast treatment that can be performed under local anaesthesia in connection with routine diagnostic angiography. In addition, SA provides much less wound complications than observed after removal of the great saphenous vein.

With few exceptions (McCarthy *et al.*,[7]), other investigators have found SA to be durable. However, none of the reported series have carried out complete surveillance to evaluate the long-term patency of the procedures. Instead the investigators have choosen to report symptomatic or hemodynamic patency. However, the absence of clinical events is not equivalent to anatomical patency of the SA. In our studies, we have shown that the primary patency rates checked by US-Doppler were 61% at 24 months. These results are respectable and far better than achieved with transluminal angioplasty, although not as good as saphenous bypass. We can conclude that patency rates reached by SA for treatment of long femoro-popliteal lesions (TASC D) are intermediary between those obtained with saphenous bypass (66 and 80% at 5 years for critical limb ischaemia and claudication, respectively[2]) and transluminal angioplasty (occlusions > 3 cm: 37% at 2 years;[9] occlusions > 5 cm, 4% at 6 months,[10] occlusions of mean length of 16.5 cm: 22% at 1 year.[11]).

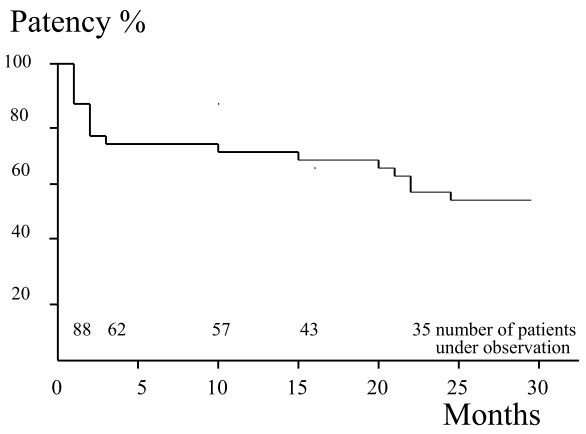


**Fig. 2.** Primary patency curve by life table method.

However, the durability of SA may be affected by a 17% incidence at 2 years of reocclusions and restenosis. Fortunately, most of these abnormalities do not lead to symptoms and only five secondary PTA and two bypasses were performed. Thus, these abnormalities do not reflect the clinical status and may explain the good 'clinical patency' reported by Bolia *et al*. Even if a PTA site does re-stenose or re-occlude, the limb may remain asymptomatic and viable probably due to the development of collaterals.

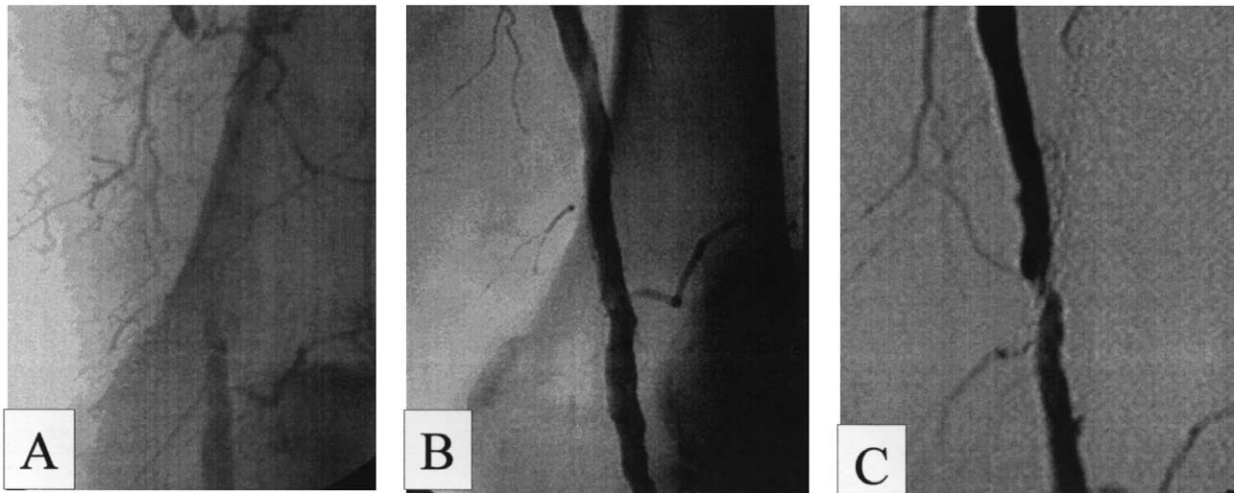


**Fig. 3.** (A) 6 cm popliteal occlusion; (B) completion angiogram after subintimal angioplasty; (C) restenosis that was further re-dilated. Subintimal angioplasty: doable and rather durable.

Because of the initial high technical success and the respectable mid-term durability, should we advocate SA as a first-line therapy in all the femoro-popliteal/-tibial occlusions? At the beginning of our experience, we reserved this technique to selected patients: after unsuccessful transluminal angioplasty of lesions inferior to 5 cm; patients with longer lesions in the absence of vein and/or with severe comorbidities or short life expectancy. In this group of patient, although surgery may provide a better anatomic patency, this may not translate into clinical outcome because many patients may not live long enough to reap the benefits. At the present time, we have expanded the selection of the patient giving more attention to the anatomical factors, such as the avoidance of a heavily calcified vessel, the presence of a good starting stump and a correct distal landing vessel.

Another question remains: does a failed SA jeopardize subsequent surgical reconstruction? Although, we did not loose any limbs due to a complication of the technique itself, in four cases the re-entry site was far lower than scheduled, with the requirement in three to perform a below knee rather than an above knee bypass.

## References

1 Transatlantic Inter-Society Consensus (TASC), Management of peripheral arterial disease. Recommendation n°35. *J Vasc Surg (Suppl)* 2000; **31**:S104.
2 Hunink MG, Wong JB, Donaldson MC, Meyerovitz MF, de Vries J, Harrington DP. Revascularization for femoropopliteal disease: a decision and cost-effectiveness analysis. *JAMA* 1995; **274**:165–171.
3 Bolia A, Miles KA, Brennan J, Bell PRF. Percutaneous transluminal angioplasty of occlusions of the femoral and popliteal arteries by subintimal dissection. *Cardiovasc Intervent Radiol* 1990; **13**:357–363.
4 Nydahl S, Hartshorne T, Bell PR, Bolia A, London NJ. Subintimal angioplasty of infrapopliteal occlusions in critically ischaemic limbs. *Eur J Vasc Endovasc Surg* 1997; **14**:212–216.
5 London NJ, Srinivasan R, Naylor AR, Hartshorne T, Ratliff DA, Bell PR, Bolia A. Subintimal angioplasty of femoropopliteal artery occlusions: the long-term results. *Eur J Vasc Surg* 1994; **8**:148–155.
6 Reekers JA, Kromhout JG, Jacobs MJHM. Percutaneous intentional extraluminal recannalisation of the femoro-popliteal artery. *Eur J Vasc Surg* 1994; **8**:723–728.
7 McCarthy RJ, Neary W, Rowbottom C *et al*. Short term results of femoropopliteal subintimal angioplasty. *Br J Surg* 2000; **87**: 1361–1365.
8 Vraux H, Hammer F, Verhelst R, Goffette P, Vandeleene B. Subintimal angioplasty of tibial vessel occlusions in the treatment of critical limb ischaemia: mid-term results. *Eur J Vasc Endovasc Surg* 2000; **20**:441–446.
9 Gallino A, Mahler F, Probst P, Nachbur B. Percutaneous transluminal angioplasty of the arteries of the lower limbs: a 5 year follow-up. *Circulation* 1984; **70**:619–623.
10 Currie IC, Wakeley CJ, Cole SE, Wyatt MG, Scott DJ, Baird RN, Horrocks M. Femoropopliteal angioplasty for severe limb ischaemia. *Br J Surg* 1994; **81**:191–193.
11 Gray BH, Olin JW. Limitations of percutaneous transluminal angioplasty with stenting for femoropopliteal arterial occlusive disease. *Semin Vasc Surg* 1997; **10**:8–16.

*Accepted 25 February 2004*